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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARK J. COOPER, MURALI K. PASUMARTHY,
TOMASZ H. KOWALCZYK, and MAUREEN COSTELLO

Appeal 2010-003421
Application 10/656,192
Technology Center 1600

Before LORA M. GREEN, MELANIE L. McCOLLUM, and
JEFFREY N. FREDMAN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 1-5, 8-14, 17-19, 26, 28, 30, 31, 34, 35, 38-40, 51-55, 58-70, 73-82, 103, 104, 106, 107, 114, 115, and 122. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claim 1 is representative of the claims on appeal, and reads as follows:

> 1. A non-naturally occurring composition comprising a plurality of unaggregated nucleic acid complexes, wherein individual complexes of said plurality consist essentially of a single nucleic acid molecule and one or more polycation molecules, wherein said complexes are formed by mixing said nucleic acid molecule and said polycation molecules, wherein prior to mixing said polycation molecules have a counterion selected from the group consisting of acetate, bicarbonate, and chloride, wherein a subset of said complexes are rod-shaped when visualized by transmission electron microscopy, wherein the rod-shaped complexes have a diameter of 10-20 nm when visualized by transmission electron microscopy, wherein the nucleic acid molecules of the rod-shaped complexes are condensed, and wherein said complexes are colloidally stable in normal saline.

Claims 8, 17, 26, and 28 are the other independent claims on appeal, and also require that a subset of the nucleic acid complexes be rod-shaped wherein the rod-shaped complexes have a diameter of 10-20 nm when visualized by transmission electron microscopy, wherein the nucleic acid molecules of the rod-shaped complexes are condensed.

The following grounds of rejection are before us for review:

I. Claims 1, 2, 8, 9, 11, 12, 17, 18, 26, 28, 30, 34, 38, and 103 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hanson.[1]

II. Claims 3, 10, 19, 31, 35, 51-53, 63-65, 67, 68, 76-78, and 104 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hanson, Park,[2] and Schacht.[3]

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[1] Hanson et al., US 5,844,107, issued Dec. 1, 1998.

III. Claims 58-62, 66, 73-75, 79-82, and 122 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hanson, Park, and Schacht as further combined with Mao.[4]

IV. Claims 4-7, 13, 14, 39, 40, 54, 55, 69, 70, 106, 107, 114, and 115 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hanson, Park, and Schacht as further combined with Kwoh.[5]

We reverse all of the above rejections.

ISSUE

Has the Examiner established by a preponderance of the evidence that Hanson anticipates a nucleic acid composition wherein a subset of the nucleic acid complexes are rod-shaped wherein the rod-shaped complexes have a diameter of 10-20 nm when visualized by transmission electron microscopy, wherein the nucleic acid molecules of the rod-shaped complexes are condensed?

FINDINGS OF FACT

FF1 The Examiner's statement of the anticipation rejection may be found at pages 6-13 of the Answer.

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[2] Park et al., US 6,177,274 B1, issued Jan. 23, 2001.
[3] Schacht et al., WO 98/19710, published May 14, 1998.
[4] Mao et al., Chitosan-DNA nanoparticles as gene carriers: synthesis, characterization and transfection efficiency, 70 J. CONTROLLED RELEASE 399-421 (2000).
[5] Kwoh et al., Stabilization of poly-L-lysine/DNA polyplexes for in vivo gene delivery to the liver, 1444 BIOCHIMICA ET BIOPHYSICA 171-190 (1998).

FF2 The Examiner notes that the claims require "that the complex is formed using a counterion selected from the group consisting of acetate, bicarbonate and chloride," finding that Hanson teaches "condensation of DNA-poly-L-lysine complexes using sodium chloride (col. 21, lines 10), thereby anticipating the counterion limitation" (Ans. 7).

FF3 As to the diameter of 10-20 nm for the rod-shaped form of the composition, the Examiner finds that Hanson teaches "'electron microspopic results have been indicated as follows: the association of the polycation with the DNA results in . . . the structure resulting from the condensation are rod-like relaxed toroids of increased size (relaxed)' (col. 62, lines 51-54)" (id. at 7-8).

FF4 According to Hanson:

> Condensed DNA is in a state in which interaction with the solvent is minimal and therefore the DNA is in the form of isolated spheres or toroids. It is not fibrous to an appreciable degree. Relaxed DNA, typically formed by dissociation of polycation from the DNA, forms fibers. Aggregated DNA forms clumped or multimolecular toroids.

(Hanson, col. 19, ll. 60-65.)

PRINCIPLES OF LAW

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). In general, a limitation is inherent if it is the "'natural result flowing from'" the explicit disclosure of the prior art. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). "Inherency . . . may not be established

by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *MEHL/Biophile Int'l. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999)(quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)).

ANALYSIS

Initially, Appellants note that the claims were subject to a restriction and election of species, wherein the species is limited to an acetate counterion, cDNA nucleic acid molecule, and the CK15-60P10 polycation (App. Br. 2, n. 1). According to Appellants, "examination has been limited to the elected species, and the requirement has not been withdrawn" (Reply Br. 2). As our review of the record concurs with Appellants' understanding, and as the Examiner did not point to where the restriction/election of species requirement had been withdrawn (see Office Communication dated January 12, 2010), we limit our review of the merits of the Appeal to the elected species.

Appellants assert that the Examiner relies on inherency in finding that Hanson teaches the claimed nucleic acid complexes (App. Br. 7). Appellants assert that reliance on the identity of procedures in making the products is incorrect, as the claimed complexes are limited to acetate as the counterion, whereas Hanson uses chloride as the counterion (id. at 10-12).

Appellants also argue that Hanson teaches three components:

1. aggregate complexes of increased size (>60 nm) (Aggregated)
2. rod-like relaxed toroids of increased size (Relaxed)
3. proper condensation (toroids <30 nm in diameter) (Condensed).

(App. Br. 8.) Appellants assert that the structure relied upon by the Examiner is not the same as that claimed as it is relaxed, whereas all of the independent claims on appeal require a condensed rod-shaped complex (Reply Br. 4).

We agree with Appellants. Specifically, we agree that the limitation that a subset of the nucleic acid complexes are rod-shaped wherein the rod-shaped complexes have a diameter of 10-20 nm when visualized by transmission electron microscopy, wherein the nucleic acid molecules of the rod-shaped complexes are condensed is not disclosed, either expressly or inherently, in Hansen. The portion of Hanson the Examiner relies upon refers to complexes of a nucleic acid molecule and polycation, wherein the complexes are in a relaxed state. As taught by Hanson, the condensed complexes are in the form of isolated spheres or toroids, and it's the relaxed complexes that form rod-liked fibers (see Hanson, cols. 57-58, Table 103). As the Examiner has not explained how the relaxed rod-like complexes of Hanson read on the condensed complexes required by the independent claims on appeal, we are compelled to reverse the anticipation rejection. We also agree that since Hanson uses sodium chloride, not acetate, as the counterion, there is no identity of procedure upon which the Examiner may rely.

We note that the Examiner has relied upon Martin for teaching that in the complexes taught by Martin,[6] the ring (toroid) and rod-like structures exist dynamically, reversing between the two structures (Ans. 29). We do

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[6] Martin et al., Observation of DNA-polymer condensate formation in real time at a molecular level, 480 FEBS LETTERS 106-112 (2000).

not find that Martin demonstrates that the compositions of Hanson inherently contain a subset of the nucleic acid complexes that are rod-shaped, wherein the rod-shaped complexes have a diameter of 10-20 nm when visualized by transmission electron microscopy, wherein the nucleic acid molecules of the rod-shaped complexes are condensed, for the reasons set forth by Appellant (see App. Br. 11-12 and 14-15).

As to the obviousness rejections, as the Examiner did not rely on the additionally cited references to remedy the above deficiencies of Hanson, we are compelled to reverse those rejections as well.

CONCLUSION OF LAW

We conclude that the Examiner has not established by a preponderance of the evidence that Hanson anticipates a nucleic acid composition wherein a subset of the nucleic acid complexes are rod-shaped wherein the rod-shaped complexes have a diameter of 10-20 nm when visualized by transmission electron microscopy, wherein the nucleic acid molecules of the rod-shaped complexes are condensed. We thus reverse all of the rejections on appeal.

REVERSED

LMG

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